

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II)
OF THE PATENT COOPERATION TREATY
(PCT Rules 44bis.3(c) and 72.2)

Date of mailing (day/month/year)
11 May 2006 (11.05.2006)

Applicant's or agent's file reference
83132P WO

International application No.
PCT/EP2004/006320

Applicant

MEDICAL ENZYMES AG et al

To:

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19. MAI 2006

Frist:

IMPORTANT NOTIFICATION

International filing date (day/month/year)
11 June 2004 (11.06.2004)

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Ellen Moyse

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Facsimile No.+41 22 338 89 75

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PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 33132P WO	FOR FURTHER ACTION	
	See item 4 below	
International application No. PCT/EP2004/006320	International filing date (day/month/year) 11 June 2004 (11.06.2004)	Priority date (day/month/year) 11 June 2003 (11.06.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MEDICAL ENZYMES AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I Basis of the report
<input checked="" type="checkbox"/>	Box No. II Priority
<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI Certain documents cited
<input type="checkbox"/>	Box No. VII Certain defects in the international application
<input type="checkbox"/>	Box No. VIII Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.3).

Date of issuance of this report
01 May 2006 (01.05.2006)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Authorized officer Ellen Moyse Telephone No. +41 22 338 89 75
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference 33132P WO		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/EP2004/006320	International filing date (day/month/year) 11.06.2004	Priority date (day/month/year) 11.06.2003
International Patent Classification (IPC) or both national classifications and IPC		
Applicant MEDICAL ENZYMES AG		

<p>1. This opinion contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Rasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>
<p>2. FURTHER ACTION</p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>

Name and mailing address of the ISA/BP	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International application No. PCT/EP2004/006320
Box No. 1 Basis of this opinion		
1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. <input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).		
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of: a. type of material <input type="checkbox"/> a sequence listing <input type="checkbox"/> table(s) related to the sequence listing b. format of material <input type="checkbox"/> in written format <input type="checkbox"/> in computer readable form c. time of filing/furnishing <input type="checkbox"/> contained in the international application as filed. <input type="checkbox"/> filed together with the international application in computer readable form. <input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.		
3. <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.		
4. Additional comments:		

Form PCT/ISA/237 (Box No. 1) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International application No. PCT/EP2004/006320
Box No. II Priority		
<p>1. <input checked="" type="checkbox"/> The following document has not yet been furnished:</p> <p><input checked="" type="checkbox"/> copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).</p> <p><input type="checkbox"/> translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).</p> <p>Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.</p> <p>2. <input type="checkbox"/> This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the International filing date indicated above is considered to be the relevant date.</p> <p>3. Additional observations, if necessary:</p>		

Form PCT/ISA/237 (Box No. II) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International application No. PCT/EP2004/006320
Box No. V	Reasoned statement under Rule 43(b)(x)1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement		
Novelty (N)	Claims	1-9
	Claims	_____
Inventive step (IS)	Claims	1-9
	Claims	_____
Industrial applicability (IA)	Claims	1-9 (see text)
	Claims	_____
2. Citations and explanations:		
<p>1. The application states that an unexpected synergistic effect exists for the combination of glutaminase with antineoplastic anthracyclines or platinum complexes.</p> <p>When there is a synergistic effect, the combination of drugs (A + B) has a superadditive effect compared with the purely computational combination of the effects of A plus B; e.g. effect of A = 20% and of B = 30%, whereas the combination (the combination product) (A + B) yields an effect of 80%.</p> <p>It must be taken into account in the interpretation of the data according to the figures that the growth is indicated therein in %. The effect achieved by the drugs must therefore be calculated using (100 - %).</p> <p>2. Hence, the effects (= growth inhibition) of the drugs emerge for mitomycin and CNS SF-539 cells (fig. 1) as being:</p> <p>glutaminase (100-21) = 79%</p> <p>mitomycin (100-99) = 1%</p>		

Form PCT/ISA/237 (Box No. V) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International application No. PCT/EP2004/006320
Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
<p>total = 80%</p> <p>(glutaminase + mitomycin) = (100 - 7) = 93%</p> <p>Comparison of the total (80%) with the actually achieved combination effect (97%) shows that a synergistic effect is present in this case.</p> <p>The same is true approximately for mitoxanthrone on breast MCF7 cells according to fig. 2 and for cis-platin on MCF7 cells according to fig. 3.</p> <p>3. Since there appears to be no relevant prior art, the subject matter of claims 1-9 is regarded as novel and inventive.</p> <p>4. The description should be made consistent with the claims. Accordingly, only the chemotherapeutic agents mentioned in the claims as agents suitable for combination products should remain in the description. There is no evidence of a synergistic effect for any chemotherapeutic agents other than those mentioned in the claims.</p> <p>5. The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claim 9 in its present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.</p>		

Form PCT/ISA/237 (Box No. V) (January 2004)

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